

EPA REGISTRATION NUMBER 42750-135 Vol. 3



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 8, 2015

Morris Gaskins
Registration Manager
Albaugh, LLC
P.O. Box 2127
Valdosta, GA 31604-2127

Subject: Label Amendment – minor change
Product Name: Oxyfluorfen TGAI
EPA Registration Number: 42750-135
Application Date: 5-29-15
Decision Number: 505608

Dear Mr. Gaskins:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

Page 2 of 2
EPA Reg. No. 42750-135
Decision No. 505608

with FIFRA section 6. If you have any questions, please contact Erik Kraft by phone at 703-308-9358, or via email at kraft.erik@epa.gov.

Sincerely,

A handwritten signature in cursive script, appearing to read "Heather Garvie".

Heather Garvie, Product Manager 24
Fungicide and Herbicide Branch
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

EDITOR'S NOTE: 6/8/15 draft label amendment to prohibit residential use

OXYFLUORFEN TGA1

For Manufacturing Use Only

ACCEPTED

06/08/2015

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under

EPA Reg. No. 42750-135

ACTIVE INGREDIENT:

Oxyfluorfen: 2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl) benzene 97.0%

OTHER INGREDIENTS: 3.0%

TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID	
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything to an unconscious person.
NOTE TO PHYSICIAN: Evacuation of the stomach might be advisable.	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may contact 1-800-424-9300 day or night, for emergency medical or transport information.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if Swallowed. Causes Moderate Eye Irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

EPA Reg. No. 42750-135

EPA Est. No. xxxxxx-xxx-xxx

NET CONTENTS: ____ Kg.

Manufactured For:
ALBAUGH, LLC
ANKENY, IA 50021

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, ocean or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE: Keep away from fire and sparks. Store in a cool, dry and well-ventilated area.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Non-refillable container. DO NOT reuse or refill this container.

Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. If not emptied in this manner, the liner may be considered an acute hazardous waste and disposed in accordance with local, state and federal regulations.

When completely empty, offer for recycling, if available, or dispose of liner in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. If drum or other outer container is contaminated and cannot be reused, dispose of in the manner required for its liner.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into a herbicide for the following use(s):

Artichokes (globe), broccoli, cabbage, cauliflower. Cacao, citrus (non-bearing), coffee, conifers (seedbeds, transplants, container stock) and selected deciduous trees, corn, cotton, cottonwood, eucalyptus, fallow bed (cotton/soybeans), fallow land, garbanzo beans, garlic, guava (Hawaii only), horseradish, jojoba, mint, onions, onions grown for seed, papayas (Hawaii only), soybeans, taro, and tree fruit, nuts, and vines (which includes almond, apple, avocado, beechnut, brazil nut, butternut, cashew, chestnut, chinquapin, crabapple, date, feijoa, fig, filbert, grapes, hickory nut, kiwi, loquat, macadamia nut, mayhaw, nectarines, olives, peach, pear, pecan, persimmon, pistachio, plum, pomegranates, prune, quince, walnut).

Do not formulate into products intended for residential uses.

This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).

It is the responsibility of the formulator to supply data to EPA to support all claims listed on the formulator's label covering all directions for use. Formulators should consult Albaugh for formulation information.

NOTE: OXYFLUORFEN TGAI should be melted by holding at 110° C for 48 hours. DO NOT HEAT ABOVE 200° C (PRODUCT DECOMPOSES)

WARRANTY LIMITATIONS AND DISCLAIMER

ALBAUGH warrants that at the time of delivery, the product will conform to its chemical description on the label, that it will pass without objection in the trade under the contract description, that seller will convey good title thereto, and that such product will be delivered free from any lawful security interest, lien or encumbrance.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW ALBAUGH EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND, EXCEPT AS SET FORTH IN THE ABOVE PARAGRAPH, ANY OTHER EXPRESS OR IMPLIED WARRANTIES. Buyer acknowledges the use of its own independent skill and expertise in the selection and use of the product and does not rely on any oral or written statements or representations.

Fed-X

May 29, 2015

Document Processing Desk (AMEND)
Ms. Heather Garvie (PM 24)
Registration Division
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard (South Bldg)
2777 South Crystal Dr.
Arlington, VA 22202

RE: Oxyfluorfen TGA
EPA Reg. No. 42750-135

Dear Ms. Garvey,

The enclosed submission for the above reference registration is a label amendment to add a restriction against formulation into products for residential use. The proposed text is noted with underlined bold text in the Directions for Use section,

This proposed label amendment is being made in coordination with Dow Agrosiences and Adama, the other oxyfluorfen technical registrants, as part of a proactive risk reduction effort in response to the Registration Review risk assessment.

The following documents are enclosed:

- 8570-1 application form
- Proposed "marked" draft label (3 hard copies)
- Proposed "marked" draft label (PDF on CD)

Please call if you have any questions.

Regards,



Morris Gaskins
Registrations Manager
Albaugh, LLC
229-244-3288



Reg Number: 42750-135

Reg. Type: Product Registration - Section 3

Status: Conditionally Registered (03-Nov-2

Name: OXYFLUORFEN TGAI

[<View Registration Details>](#)

(No New Receipts)

S:	Submission Type	OPP Rec'd Date	Resubmission	Description
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...Decisions...

D: Pending; 505608; 42750-135;300;LABEL REV

75-Day Letters

S: 969185 6/1/2015; Amendment: 42750

Data Requirements

D: Closed; 468706; 42750-135;R340;NON-FAS

D: Closed; 449628; 42750-135;300;LABEL REV

D: Closed; 448178; 42750-135;332;NOTIFICAT

D: Closed; 363862; 42750-135;R31;NEW PROC

S: 969185 Reg #: 42750-135

Submission Type: Amendment

Resubmission?: ☐ Yes ☒ No

E-Sub #:

Decision #: 505608; 300;LABEL REVISION;NO DATA REQUIRED;

Submitter Company: ALBAUGH, LLC

Application Date: 29-May-2015

OPP Received Date: 01-Jun-2015

Date Sent to Risk manager: 02-Jun-2015

Studies Included?: ☐ Yes ☒ NoFast Track?: ☒ Yes ☐ NoForm A Signed?: ☐ Yes ☐ No ☒ None

Date:

Form B Signed?: ☐ Yes ☐ No ☒ None

Date:

Reviewer: Kraft, Erik

Received DT:

Editable Due DT:

Submission Due DT: 30-Aug-2015 Response: 0, 01-Jun-2015

Priority Weight:

Priority Points:

Comments: fast track amendment / add a restriction against formulation into products for residential use

JUN 3 - 2015

FAST-TRACK AMENDMENTS – Completeness Screening Checklist

S. MEADOWS

Expert's In-Processing Signature:

~~42750-135~~

Date:

6/3

PM #:

24

EPA Reg. Number: 42750-135		EPA Receipt Date: 6/1/15		
	Checklist Item	Yes	No	N/A
1	Application Form (EPA Form 8570-1) - signed?	✓		
2	Confidential Statement of Formula (EPA Form 8570-29) - signed?			✓
3	Certification with Respect to Citation of Data (EPA Form 8570-34) - signed?			✓
4	Formulator's Exemption Statement (EPA Form 8570-27) - signed?			✓
5	Data Matrix (EPA Form 8570-35) [Applicable for adding me-too uses] - signed?			✓
	a) Selective Method?			
	b) Cite-All Method?			
	c) Public copy of Matrix provided? See PR Notice 98-5			
6	Is Label included? (5 copies)	✓		
	a) Electronic Label submitted?	✓		
Comments: RESPONSE TO REG. REVIEW.				

S: 969185

Milestone Email:

Regulatory Type: Product Registration - Section 3

Application Type: Amendment

Company: 42750 ALBAUGH, LLC

Risk Manager: Registration Division, Risk Management Team 24

Product #: 42750-135 Product Name: OXYFLUORFEN TGA

Override#:

Me Too
Section3:

Me Too Product
Name:

Application Date: 29-May-2015

OPP Rec'd Date: 01-Jun-2015

Front End Date: 01-Jun-2015

Risk Manager Send Date: 02-Jun-2015

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

AMENDMENT

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Resubmission: ☐ Yes ☒ No

Fee For Service: ☐ Yes ☒ No

Billable: ☐ Yes ☒ No

V

Print Letter

Enter More Information

Tracking

Receipt Content

Paper Label

Electronic Label

TTT

View/Edit

New Ingredient

Request Date:

New Ingredient

Received Date:



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 2, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MR. MORRIS GASKINS
ALBAUGH, LLC
PO Box 2127
VALDOSTA, GA 31604-2127

PRODUCT NAME: OXYFLUORFEN TGAI
COMPANY NAME: ALBAUGH, LLC
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 42750-135
EPA RECEIPT DATE: 06/01/15

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 24, at (703) 308-0034.

Sincerely,

A handwritten signature in black ink, appearing to be "S. [unclear]".

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division



Fee for Service

{969185N~

This package includes the following

☐ New Registration

☒ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. **24**

Receipt No.

S-

969185

EPA File Symbol/Reg. No.

42750-135

Pin-Punch Date:

6/1/2015

☒ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ ____

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer:

Jennifer Gaines

Date: 6/2/15

Remarks:



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 42750-135	2. EPA Product Manager H. Garvey	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Oxyfluorfen TGA1	PM# 24	
5. Name and Address of Applicant (Include ZIP Code) Albaugh LLC P.O. Box 2127 Valdosta, GA 31604 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Proposed label amendment to add statement that prohibits formulation into products for residential use.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
* Certification must be submitted				Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container bulk		5. Location of Label Directions <input checked="" type="checkbox"/> On label attached to container	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Morris Gaskins		Title Registrations Manager		Telephone No. (Include Area Code) 229-244-3288	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Case Application Received (Stamped)
2. Signature 		3. Title Registrations Manager			
4. Typed Name Morris Gaskins		5. Date May 29, 2015			

OXYFLUORFEN TGA1

For Manufacturing Use Only

ACTIVE INGREDIENT:

Oxyfluorfen: 2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl) benzene 97.0%

INERT INGREDIENTS: 3.0%

TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Evacuation of the stomach might be advisable.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may contact 1-800-424-9300 day or night, for emergency medical or transport information.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if Swallowed. Causes Moderate Eye Irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

EPA Reg. No. 42750-135

EPA Est. No. xxxxxx-xxx-yxx

NET CONTENTS: ____ Kg.

Manufactured For:
ALBAUGH, INC.
ANKENY, IA 50021

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, ocean or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE: Keep away from fire and sparks. Store in a cool, dry and well-ventilated area.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Non-refillable container. DO NOT reuse or refill this container.

Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. If not emptied in this manner, the liner may be considered an acute hazardous waste and disposed in accordance with local, state and federal regulations.

When completely empty, offer for recycling, if available, or dispose of liner in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. If drum or other outer container is contaminated and cannot be reused, dispose of in the manner required for its liner.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into a herbicide for the following use(s):

Artichokes (globe), broccoli, cabbage, cauliflower. Cacao, citrus (non-bearing), coffee, conifers (seedbeds, transplants, container stock) and selected deciduous trees, corn, cotton, cottonwood, eucalyptus, fallow bed (cotton/soybeans), fallow land, garbanzo beans, garlic, guava (Hawaii only), horseradish, jojoba, mint, onions, onions grown for seed, papayas (Hawaii only), soybeans, taro, and tree fruit, nuts, and vines (which includes almond, apple, avocado, beechnut, brazil nut, butternut, cashew, chestnut, chinquapin, crabapple, date, feijoa, fig, filbert, grapes, hickory nut, kiwi, loquat, macadamia nut, mayhaw, nectarines, olives, peach, pear, pecan, persimmon, pistachio, plum, pomegranates, prune, quince, walnut).

Do not formulate into products intended for residential uses.

This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).

It is the responsibility of the formulator to supply data to EPA to support all claims listed on the formulator's label covering all directions for use. Formulators should consult Albaugh for formulation information.

NOTE: OXYFLUORFEN TGAI should be melted by holding at 110° C for 48 hours. DO NOT HEAT ABOVE 200° C (PRODUCT DECOMPOSES)

WARRANTY LIMITATIONS AND DISCLAIMER

ALBAUGH warrants that at the time of delivery, the product will conform to its chemical description on the label, that it will pass without objection in the trade under the contract description, that seller will convey good title thereto, and that such product will be delivered free from any lawful security interest, lien or encumbrance.

ALBAUGH EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND, EXCEPT AS SET FORTH IN THE ABOVE PARAGRAPH, ANY OTHER EXPRESS OR IMPLIED WARRANTIES. Buyer acknowledges the use of its own independent skill and expertise in the selection and use of the product and does not rely on any oral or written statements or representations.

Material Sent for Data Extraction

Reg. # 42750-135

Description: CSF Amendment

☒ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated _____

☐ Notification Dated _____

☒ New CSF(s) Dated 8-15-12

☐ Other: _____

☒ Decision #: 468706

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Emily Hartman

Phone: 703-347-0189 Division: RD

Date: 12-26-12



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Morris Gaskins
Albaugh, Inc.
P.O. Box 2127
Valdosta, GA 31604-2127

Subject: Confidential Statement of Formula (CSF) Amendment
Product Name: Oxyfluorfen TGAI
EPA Registration Number: 42750-135
Application Date: August 15, 2012

Dear Mr. Morris,

The Amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended is acceptable.

The Alternate CSF (Alternates #1), dated August 15, 2012 is acceptable and have been added to your record.

A complete copy of the review outlining this determination has been included with this letter for your information.

If you have any questions, please contact Emily Hartman of my staff at (703) 347-0189 or hartman.emily@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kathryn V. Montague", written over a circular stamp or seal.

Kathryn V. Montague, Product Manager 23
Herbicide Branch
Registration Division
Office of Pesticide Programs

Enclosed: D405340



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DECISION NO: 468706 DP BARCODE: 405340
PRODUCT: Oxyfluorfen TGA PCC: 111601

EPA REG. NO.: 42750-135
REGISTRANT: Albaugh Inc

Date: December 06, 2012

SUBJECT: Oxyfluorfen TGA

FROM: Akiva Abramovitch, Ph. D.
Product Chemistry Team
Technical Review Branch / Registration Division (7505P)

Bruce Kitchens 12/12/12
12/12/12

TO: Tracy White/Kathryn Montague, PM 23
Herbicide Branch / Registration Division (7505P)

*Product ingredient source
information may be entitled to
confidential treatment*

INTRODUCTION:

The registrant has submitted a Confidential Statement of Formula (CSF) for an alternate manufacturing site in [REDACTED] dated August 15, 2012. The basic formulation dated January 16, 2006 is for a production facility in [REDACTED]

The 830 Series Subgroup A data that include a five batch analysis have been submitted under the MRID Nos. 489099-01 and -02, for the alternate CSF #1 dated 8/15/12.

The Technical Review Branch (TRB) has been asked to evaluate the new submission to determine if the submitted data and studies will support the new manufacturing site of the subject product.

SUMMARY OF FINDINGS:

1. The nominal concentration (97.0%) of the AI (oxyfluorfen) concurs with the product label claim nominal concentration of 97.0%. The product chemistry data submitted corresponding to guideline reference 830.1550 (product identity & composition) and 830.1750 (certified limits) satisfy the data requirements of 40CFR§158.320 and 158.345, respectively.
2. The subject product is produced in an integrated system described in MRID No. 489099-01 detailing the production and manufacturing processes corresponding to guidelines 830.1600 and 830.1620.
3. The registrant has provided an adequate explanation of the impurities that are known to be associated with the subject product and potential impurities of the subject product. This submitted data corresponding to guideline 830.1670 (discussion on the formation of impurities) satisfy the data requirements of 40CFR§158.340. The preliminary 5-batch analysis provided by the registrant concurs with the data the registrant presented on the impurities. [MRID No. 489099-01 and -02]
4. The product chemistry data submitted corresponding to the guideline reference 830.1700 (preliminary analysis) satisfy the data requirements for 40CFR§158.345. The % AI and the impurities were determined for the test substance. See the Confidential Appendix for details. [MRID No. 489099-02]

DECISION NO: 468706

DP BARCODE: 405340

EPA REG. NO.: 42750-135

PRODUCT: Oxyfluorfen TGAi

PCC: 111601

REGISTRANT: Albaugh Inc

5. The data submitted corresponding to reference guideline 830.1800 (Enforcement Analytical Method) satisfies the data requirements of 40CFR§158.355. The method of analysis of the active ingredient (AI) is high-performance liquid chromatography (HPLC) with UV detection (225 nm). The method was validated for precision, linearity, and accuracy. Details of the method follow. [MRID No. 489099-02]

CONCLUSIONS:

TRB has reviewed the product chemistry data submitted for Oxyfluorfen TGAi and has concluded that:

1. All of the product chemistry data submitted corresponding to 830 Series Subgroup A are acceptable and satisfy the data requirements of 40CFR§158.155.
2. The results of the five batch analysis support the label claim of 97% Oxyfluorfen. The impurity profile matches the the basic CSF dated January 16, 2006
3. The CSF for the alternate formulation dated August 15, 2012 is acceptable.

Common Name: Oxyfluorfen TGAi

Chemical name:

IUPAC: 2-chloro- α,α,α -trifluoro-p-tolyl-3-ethoxy-4-nitrophenyl ether

CA: 2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene

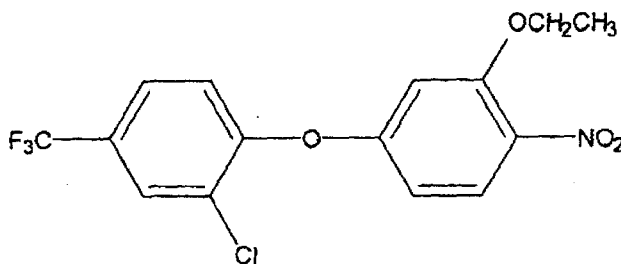
CAS No.: 42874-03-3

PC Code No.: 111601

Empirical formula: $C_{15}H_{11}ClF_3NO_4$

Molecular Weight: 361.7

Structural formula:



DECISION NO: 468706

DP BARCODE: 405340

EPA REG. NO.: 42750-135

PRODUCT: Oxyfluorfen TGA1 PCC: 111601

REGISTRANT: Albaugh Inc

Table 1: Manufacturing and Impurity Data for the Oxyfluorfen TGA1.

GLN	Requirement	MRID	Status ¹	Details and/or Deficiency
830.1550	Product Identity & Disclosure of Ingredients	489099-01	A	The nominal concentration of the AI (97.0%) concurs with the product label claim and is supported by the 5 batch analyses to be with in the certified limits.
830.1600 830.1620	Starting Materials & Manufacturing Process	489099-01	A	The MSDS for the proposed product and the starting material have been submitted. The subject product is produced in an integrated system.
830.1670	Discussion of Impurities	489099-01 and -02	A	An adequate explanation of the known and potential impurities found in the technical product has been provided.
830.1700	Preliminary Analysis	489099-02	A	The registrant has provided 5 batch analysis for the TGA1.
830.1750	Certification of Limits	489099-02	A	The registrant based the upper certified limits on the results obtained from the 5 batch analyses and manufacturing practices.
830.1800	Analytical Methods	489099-02	A	Method was submitted for determination of the %AI in the product. HPLC / UV (225 nm) detector was used for the %AI determination. The method was validated for precision, linearity and accuracy.
¹ A = Acceptable; N = Unacceptable (see Deficiency); U = Upgradable data; N/A = Not Applicable.				



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 42750-135	2. EPA Product Manager K. Montague	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Oxyfluorfen TGA1	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) Albaugh, Inc. P.O. Box 2127 Valdosta, GA 31604-2127 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amendment to add alternate manufacturing facility as CSF alternate # 1

This amendment is being submitted under the PRIA II Fee for Service program as a EPA Class # R340 application with a 4 month review time and a fee of \$3,617

A copy of the electronic payment receipt for that amount is enclosed

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container bulk		5. Location of Label Directions <input checked="" type="checkbox"/> On label attached to container	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Morris Gaskins	Title Registrations Manager	Telephone No. (Include Area Code) 229-244-3288
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Registrations Manager	
4. Typed Name Morris Gaskins	5. Date August 15, 2012	

ALBAUGH, INC.

GEORGIA OFFICE
P.O. Box 2127
Valdosta, GA 31604-2127
229.244.3288 (Phone)
229.244.5841 (FAX)

48909900

Fed-X

August 15, 2012

Document Processing Desk (AMEND)
Ms. Kathryn Montague (PM 23)
Registration Division (7504P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard (South Bldg)
2777 South Crystal Dr.
Arlington, VA 22202

Re: Oxyfluorfen TGAI
EPA Reg. No. 42750-135

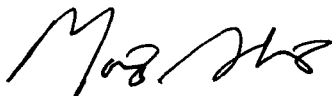
Dear Ms. Montague,

The enclosed submission is a proposed amendment for the above reference registration to add an alternate manufacturing source under CSF Alt. # 1. Documents in support of this amendment are detailed in the enclosed transmittal page.

Albaugh believes this submission qualifies as a PRIA R340 action with a 4-month review time and \$3,617 fee. A receipt of the electronic payment made to Pay.gov for that amount is enclosed.

Please call if you have any questions.

Regards,



Morris Gaskins
Registrations Manager

Agri Star®
By Albaugh, Inc.

PREMIER SUPPLIER OF OFF-PATENT CROP PROTECTION PRODUCTS
www.albaughinc.com

TRANSMITTAL DOCUMENT

Name and address of submitter:

Albaugh, Inc.
P.O. Box 2127
Valdosta, GA 31604-2127

Company Official: Morris Gaskins

Telephone: (229) 244-3288

Regulatory action for which this package is submitted:

Submission of alternate manufacturing source for OXYFLUORFEN TGAI
(EPA Reg. No. 42750-135)

Transmittal Date: August 15, 2012

List of items submitted:

- Transmittal page
- Cover letter
- 8570-1 application form
- 8570-34 Certification With Respect to Citation of Data form
- 8570-35 Data Matrix (internal use copy)
- 8570-35 Data Matrix (public file copy)
- Alternate CSF # 1 (2 copies)
- PRIA payment receipt

8909901 • Series 830-A Preliminary Analysis and Enforcement Analytical Methods (OPPTS Guidelines 830.1700 and 830.1800) (3 copies)

8909902 • Series 830-A Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Production Process, Discussion of Formation of Impurities and Certified Limits (OPPTS Guidelines 830.1550, 830.1600, 830.1620, 830.1670 and 830.1750) (3 copies)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 20, 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

ALBAUGH INC
1525 NE 36TH STREET
ANKENY, IA 50021

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 16-AUG-12. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 42750-135	2. EPA Product Manager K. Montague	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Oxyfluorfen TGA1	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) Albaugh, Inc. P.O. Box 2127 Valdosta, GA 31604-2127 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amendment to add alternate manufacturing facility as CSF alternate # 1

This amendment is being submitted under the PRIA II Fee for Service program as a EPA Class # R340 application with a 4 month review time and a fee of \$3,617

A copy of the electronic payment receipt for that amount is enclosed

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container bulk		5. Location of Label Directions <input checked="" type="checkbox"/> On label attached to container	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Morris Gaskins	Title Registrations Manager	Telephone No. (Include Area Code) 229-244-3288	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Registrations Manager	
4. Typed Name Morris Gaskins		5. Date August 15, 2012	

ALBAUGH, INC.

GEORGIA OFFICE
P.O. Box 2127
Valdosta, GA 31604-2127
229.244.3288 (Phone)
229.244.5841 (FAX)

48909900

Fed-X

August 15, 2012

Document Processing Desk (AMEND)
Ms. Kathryn Montague (PM 23)
Registration Division (7504P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard (South Bldg)
2777 South Crystal Dr.
Arlington, VA 22202

Re: Oxyfluorfen TGAI
EPA Reg. No. 42750-135

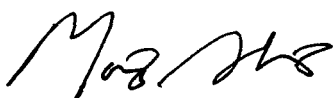
Dear Ms. Montague,

The enclosed submission is a proposed amendment for the above reference registration to add an alternate manufacturing source under CSF Alt. # 1. Documents in support of this amendment are detailed in the enclosed transmittal page.

Albaugh believes this submission qualifies as a PRIA R340 action with a 4-month review time and \$3,617 fee. A receipt of the electronic payment made to Pay.gov for that amount is enclosed.

Please call if you have any questions.

Regards,



Morris Gaskins
Registrations Manager

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By Albaugh, Inc.

PREMIER SUPPLIER OF OFF-PATENT CROP PROTECTION PRODUCTS
www.albaughinc.com

TRANSMITTAL DOCUMENT

Name and address of submitter:

Albaugh, Inc.
P.O. Box 2127
Valdosta, GA 31604-2127

Company Official: Morris Gaskins

Telephone: (229) 244-3288

Regulatory action for which this package is submitted:

Submission of alternate manufacturing source for OXYFLUORFEN TGAI
(EPA Reg. No. 42750-135)

Transmittal Date: August 15, 2012

List of items submitted:

- Transmittal page
- Cover letter
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- 8570-35 Data Matrix (internal use copy)
- 8570-35 Data Matrix (public file copy)
- Alternate CSF # 1 (2 copies)
- PRIA payment receipt

8909901 • Series 830-A Preliminary Analysis and Enforcement Analytical Methods (OPPTS Guidelines 830.1700 and 830.1800) (3 copies)

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PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 8/16/12

Experts In-Processing Signature: Elizabeth Nguyen Date 8/17/12

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>42750-135</u>		EPA Receipt Date: <u>8/16/12</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			✓		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			✓		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
	No inerts					
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			✓		
	Certificate and data matrix consistent			✓		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					✓
	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			✓		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	✓				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)				✓	

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	✓		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			✓
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			✓
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

- * Active and impurities only. No inerts to review.
- * Studies passed PRN 11-03 review.
In Study #1, pgs 19-26 in the non-confidential part had confidentiality claims. The registrant removed those markings and resend the pages.
- * Amendment passed.

AB

MRID : 489099

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Script for Rejection Phone calls

Contact Name: Morris Gaskins

Phone #: 229-244-3288

Email: *morrisg@albanyinc.com*

^{email}
First Call/Initials: AB

Date: 08/20/12

Time: 8:31 AM

Second Call/Initials:

Date:

Time:

This is Aswathy Balan, EPA contractor.

Passed

I'm calling regarding your submission in support of

Ref # 42750-135.

We have found the following deficiencies regarding:

PR Notice 86.5: Yes or No

Volume/Study Title:

Study #1 : Pgs 19-26 have confidential markings

Volume/Study Title:

Volume/Study Title:

Additional volumes continued on back of page: Yes or No

Application Package: Yes or No

These deficiencies have been approved by EPA.

The corrections can be faxed to 703-305-5060/Attn: Aswathy Balan.

Second Call/Email:

If we do not receive the corrections by _____, we will process your submission, accordingly. Please direct all future calls and correspondence to the appropriate EPA Risk Manager.



Oxyfluorfen TGA I (Reg# 42750-135)

Ailis Gregory

to:

Aswathy Balan

08/20/2012 09:52 AM

Cc:

Morris Gaskins

Hide Details

From: Ailis Gregory <AilisG@albaughinc.com>

To: Aswathy Balan/DC/USEPA/US@EPA

Cc: Morris Gaskins <MorrisG@albaughinc.com>

1 Attachment



42750-135 corrected pgs 19 to 26.pdf

Good Morning Mr. Balan.

This email is in response to an issue you raised regarding our application for Oxyfluorfen TGA I. For the study "Preliminary Analysis and Enforcement Analytical Method," please see attached the corrected pages 19-26 of the non-confidential part of the report. These pages should not have been marked as confidential.

Please let me know if you have further questions.

Ailis

Ailis Gregory

Regulatory Chemist

Albaugh, Inc.

2935 North Ashley Street

Suite 106

Valdosta, GA 31602

229-244-3288

ailisg@albaughinc.com



RE: Oxyfluorfen TGAI (Reg# 42750-135)
Morris Gaskins
to:
Aswathy Balan
08/20/2012 08:54 AM
Cc:
Sree Nair
Hide Details
From: Morris Gaskins <MorrisG@albaughinc.com>

To: Aswathy Balan/DC/USEPA/US@EPA

Cc: Sree Nair/DC/USEPA/US@EPA

Mr. Balan,

Our Regulatory Chemist, Ms. Ailis Gregory look into this and contact you to rectify.

Regards,

Morris Gaskins
Albaugh, Inc.

From: Aswathy Balan [<mailto:Balan.Aswathy@epamail.epa.gov>]
Sent: Monday, August 20, 2012 8:32 AM
To: Morris Gaskins
Cc: Sree Nair
Subject: Oxyfluorfen TGAI (Reg# 42750-135)

Dear Mr. Gaskins,

This email is to address one issue found regarding your Application for amendment of the product Oxyfluorfen TGAI (Reg# 42750-135).

*Study # 1: Preliminary Analysis and Enforcement Analytical Methods, pages 19-26 in the non-confidential part of the study has a confidentiality marking in the footer. Since all data claimed as confidential under FIFRA 10(d) (1) (A), (B), or (C) should have been removed

to the confidential attachment, you need to clarify your intentions regarding the data contained in the body of the study.

Please verify and send the revised pages either by email or to our secure fax line 703-305-5060.

Thanks,

Aswathy Balan
Macfadden, EPA Contractor
2777 S. Crystal Drive, S4810
Arlington, VA 22202
Ph: 703-347-8787
Fax: 703-305-5060



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 17, 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-468706
EPA File Symbol or Registration Number: 42750-135
Product Name: OXYFLUORFEN TGAI
EPA Receipt Date: 16-Aug-2012
EPA Company Number: 42750
Company Name: ALBAUGH INC

MORRIS GASKINS
ALBAUGH INC
P.O. BOX 2127
VALDOSTA, GA 31604-2127

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R340

NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTIONARY LABEL
STATEMENTS;SOURCE CHANGES TO AN UNREGISTERED SOURCE);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee
Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "M. J. H.", is written over the word "Sincerely,".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

NT
{922124t~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. **23**

Receipt No.

S- **922124**

EPA File Symbol/Reg. No.

42750-135

Pin-Punch Date:

8/16/2012

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

R340

Granted:

R340

Amount Due: \$ **3617⁰⁰**

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: **JPA**

Date: **8/17/12**

Remarks:

Morris Gaskins

From: paygovadmin@mail.doc.twai.gov
Sent: Tuesday, August 14, 2012 11:09 AM
To: Morris Gaskins
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at pay.gov.clev@clev.frb.org.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 257LNKLT
Agency Tracking ID: 74345861823
Transaction Type: Sale
Transaction Date: Aug 14, 2012 11:08:33 AM

Account Holder Name: James Morris Gaskins Transaction Amount: \$3,617.00 Billing Address: P.O. Box 2127
City: Valdosta
State/Province: GA
Zip/Postal Code: 31604
Country: USA
Card Type: Visa
Card Number: *****0380

Decision Number:
Registration Number: 42750-135
Company Name: Albaugh, Inc.
Company Number: 42750
Action Code: R340

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Online Payment

Online Payment

Step 3: Confirm Payment

1 | 2 | 3

Thank you.

Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 257LNKLT

Agency Tracking ID: 74345861823

Transaction Date and Time: 08/14/2012 11:08 EDT

Payment Summary

Address Information	Account Information	Payment Information
Account Holder James Morris Name: Gaskins Billing Address: P.O. Box 2127 Billing Address 2: City: Valdosta State / Province: GA Zip / Postal 31604 Code: Country: USA	Card Type: Visa Card Number: *****0380 Decision Number: Registration Number: 42750-135 Company Name: Albaugh, Inc. Company Number: 42750 Action Code: R340	Payment Amount: \$3,617.00 Transaction Date 08/14/2012 and Time: 11:08 EDT

Do you want to ☐ create a new plastic card?

Fed-X

August 15, 2012

Document Processing Desk (AMEND)
Ms. Kathryn Montague (PM 23)
Registration Division (7504P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard (South Bldg)
2777 South Crystal Dr.
Arlington, VA 22202

Re: Oxyfluorfen TGA
EPA Reg. No. 42750-135

Dear Ms. Montague,

The enclosed submission is a proposed amendment for the above reference registration to add an alternate manufacturing source under CSF Alt. # 1. Documents in support of this amendment are detailed in the enclosed transmittal page.

Albaugh believes this submission qualifies as a PRIA R340 action with a 4-month review time and \$3,617 fee. A receipt of the electronic payment made to Pay.gov for that amount is enclosed.

Please call if you have any questions.

Regards,



Morris Gaskins
Registrations Manager



PREMIER SUPPLIER OF OFF-PATENT CROP PROTECTION PRODUCTS
www.albaughinc.com

TRANSMITTAL DOCUMENT

Name and address of submitter:

Albaugh, Inc.
P.O. Box 2127
Valdosta, GA 31604-2127

Company Official: Morris Gaskins

Telephone: (229) 244-3288

Regulatory action for which this package is submitted:

Submission of alternate manufacturing source for OXYFLUORFEN TGA
(EPA Reg. No. 42750-135)

Transmittal Date: August 15, 2012

List of items submitted:

- Transmittal page
- Cover letter
- 8570-1 application form
- 8570-34 Certification With Respect to Citation of Data form
- 8570-35 Data Matrix (internal use copy)
- 8570-35 Data Matrix (public file copy)
- Alternate CSF # 1 (2 copies)
- PRIA payment receipt

- Series 830-A Preliminary Analysis and Enforcement Analytical Methods (OPPTS Guidelines 830.1700 and 830.1800) (3 copies)

- Series 830-A Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Production Process, Discussion of Formation of Impurities and Certified Limits (OPPTS Guidelines 830.1550, 830.1600, 830.1620, 830.1670 and 830.1750) (3 copies)



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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Albaugh, Inc. P.O. Box 2127 Valdosta, GA 31604	EPA Registration Number/File Symbol 42750-135
Active Ingredient(s) and/or representative test compound(s) oxyfluorfen	Date 8/15/12
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) MUP for terrestrial food use, terrestrial non-food use	Product Name Oxyfluorfen TGA1

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

8/15/12

Typed or Printed Name and Title

Morris Gaskins Registrations Manager

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DATA MATRIX

Date: 8/15/12 **EPA Reg. No./File Symbol** 42750-135 **Page** 1 of 6

Applicant's/Registrant's Name & Address: Albaugh Inc.
 1525 NE 36th St.
 Ankeny, IA 50021

Product:
Oxyfluorfen TGAI

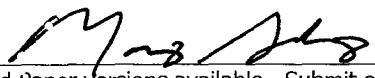
Ingredient: Oxyfluorfen CAS # 42874-03-3

Guideline Reference	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	With application	Albaugh	OWN	
830.1600	Description of Materials Used to Produce the	With application	Albaugh	OWN	
830.1620	Description of Product Process	With application	Albaugh	OWN	
830.1650	Description of Formulation Process				Waiver ²
830.1670	Description of Formation of Impurities	With application	Albaugh	OWN	
830.1700	Preliminary Analysis	With application	Albaugh	OWN	
830.1750	Certified Limits	With application	Albaugh	OWN	
830.1800	Enforcement Analytical Method	With application	Albaugh	OWN	
830.6302	Color	467359-04	Albaugh	OWN	
830.6303	Physical State	467359-04	Albaugh	OWN	
830.6304	Odor	467359-04	Albaugh	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	467359-04	Albaugh	OWN	
830.6314	Oxidation/Reduction: Chemical Incompatibility				Not req'd ¹
830.6315	Flammability				Not req'd ¹
830.6316	Explosibility				Not req'd ¹
830.6317	Storage Stability				In progress ³
Signature 			Name and Title: Morris Gaskins Registrations Manager		Date: 8/15/12

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DATA MATRIX

Date: 8/15/12			EPA Reg. No./File Symbol 42750-135		Page 2 of 6
Applicant's/Registrant's Name & Address: Albaugh Inc. 1525 NE 36 th St. Ankeny, IA 50021			Product: Oxyfluorfen TGA1		
Ingredient: Oxyfluorfen CAS # 42874-03-3					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6319	Miscibility				Not req'd ¹
830.6320	Corrosion Characteristics				In progress ³
830.6321	Dielectric Breakdown Voltage				Not req'd ¹
830.7000	pH	467359-04	Albaugh	OWN	
830.7050	UV/Visible Absorption	467359-04	Albaugh	OWN	
830.7100	Viscosity				Not req'd ¹
830.7200	Melting Point/Melting Range	467359-04	Albaugh	OWN	
830.7220	Boiling Point/Boiling Range				Waiver ⁴
830.7300	Density/Relative Density/Bulk Density	467359-04	Albaugh	OWN	
830.7370	Dissociation Constants in Water				Waiver ⁵
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				Waiver ⁶
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				Waiver ⁶
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography	467359-04	Albaugh	OWN	
Signature 			Name and Title: Morris Gaskins Registrations Manager		Date: 8/15/12

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DATA MATRIX

Date: 8/15/12	EPA Reg. No./File Symbol 42750-135	Page 3 of 6
Applicant's/Registrant's Name & Address: Albaugh Inc. 1525 NE 36 th St. Ankeny, IA 50021	Product: Oxyfluorfen TGA1	

Ingredient: Oxyfluorfen CAS # 42874-03-3

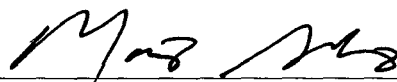
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	467359-04	Albaugh	OWN	
830.7860	Water Solubility, Generator Column Method				Waiver ⁷
830.7950	Vapor Pressure	467359-04	Albaugh	OWN	
870.1100	Acute Oral Toxicity - Rat	CITE ALL		PAY	
870.1200	Acute Dermal Toxicity - Rat	CITE ALL		PAY	
870.1300	Acute Inhalation Toxicity - Rat	CITE ALL		PAY	
870.2400	Primary Eye Irritation - Rabbit	CITE ALL		PAY	
870.2500	Primary Dermal Irritation	CITE ALL		PAY	
870.2600	Dermal Sensitization	CITE ALL		PAY	

Signature 	Name and Title: Morris Gaskins Registrations Manager	Date: 8/15/12
---------------------------------------------------------------------------------------------------------	----------------------------------------------------------------	-------------------------

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DATA MATRIX

Date: 8/15/12		EPA Reg. No./File Symbol 42750-135		Page 4 of 6	
Applicant's/Registrant's Name & Address: Albaugh Inc. 1525 NE 36 th St. Ankeny, IA 50021		Product: Oxyfluorfen TGAI			
Ingredient: Oxyfluorfen CAS # 42874-03-3					
Guideline Reference Number	Guideline Study Name	MRID	Submitter (EPA Co. No.)	Status	Note
Oxyfluorfen data requirements					
Albaugh will make offers-to-pay to the following companies that appear on the current data submitters list for Oxyfluorfen					
Oxyfluorfen Generic Data	Cite-All		Ortho/Scotts Company (239)	PAY	
Oxyfluorfen Generic Data	Cite-All		Dupont (352)	PAY	
Oxyfluorfen Generic Data	Cite-All		Monsanto (524)	PAY	
Oxyfluorfen Generic Data	Cite-All		Chemsico (9688)	PAY	
Oxyfluorfen Generic Data	Cite-All		Agan (11603)	PAY	
Oxyfluorfen Generic Data	Cite-All		Loveland Products (34704)	PAY	
Oxyfluorfen Generic Data	Cite-All		Harrell's (52287)	PAY	
Oxyfluorfen Generic Data	Cite-All		Everris (58185)	PAY	
Oxyfluorfen Generic Data	Cite-All		OGP (59807)	PAY	
Oxyfluorfen Generic Data	Cite-All		Dow Agrosciences (62719)	PAY	
Oxyfluorfen Generic Data	Cite-All		Makhteshim-Agan NA (66222)	PAY	
Signature 			Name and Title: Morris Gaskins Registrations Manager		Date: 8/15/12

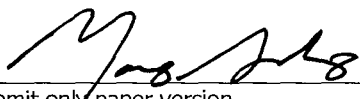
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DATA MATRIX

Date: 8/15/12		EPA Reg. No./File Symbol 42750-135		Page 5 of 6	
Applicant's/Registrant's Name & Address:		Product:			
Albaugh Inc. 1525 NE 36 th St. Ankeny, IA 50021		Oxyfluorfen TGAI			
Ingredient: Oxyfluorfen CAS # 42874-03-3					
Guideline Reference Number	Guideline Study Name	MRID	Submitter (EPA Co. No.)	Status	Note
Oxyfluorfen Generic Data	Cite-All		Spray Drift TF (66607)	PAY	
Oxyfluorfen Generic Data	Cite-All		ORETF (71754)	PAY	
Oxyfluorfen Generic Data	Cite-All		Ag Reentry TF (71755)	PAY	
Oxyfluorfen Generic Data	Cite-All		Nations Ag II (72167)	PAY	
Oxyfluorfen Generic Data	Cite-All		FIFRA ESTF (73989)	PAY	
Oxyfluorfen Generic Data	Cite-All		REJV (74888)	PAY	
Oxyfluorfen Generic Data	Cite-All		AG handlers Exposure TF (75234)	PAY	
Oxyfluorfen Generic Data	Cite-All		Gro-Pro (79676)	PAY	
Oxyfluorfen Generic Data	Cite-All		Summit Agro NA (82534)	PAY	
Oxyfluorfen Generic Data	Cite-All		Source Dynamics (82542)	PAY	
Oxyfluorfen Generic Data	Cite-All		GESTF (84653)	PAY	
Oxyfluorfen Generic Data	Cite-All		Willowood Oxyfluorfen (87283)	PAY	
Oxyfluorfen Generic Data	Cite-All		Willowood LLC (87290)	PAY	
Oxyfluorfen Generic Data	Cite-All		Glorion (87769)	PAY	
Oxyfluorfen Generic Data	Cite-All		Summit Agro USA (88783)	PAY	
Signature 			Name and Title: Morris Gaskins Registrations Manager		Date: 8/15/12

Footnote 1

- 830.6314 Oxidation/Reduction: chemical incompatibility
- 830.6315 Flammability
- 830.6316 Explodability
- 830.6319 Miscibility
- 830.6321 Dielectric Breakdown
- 830.7100 Viscosity

This data is not required for Technical Grade products per Product Properties Test Guidelines OPPTS 830.1000 (e)(2)(xi)(B) Table 2

Footnote 2

- 830.1650 Formulation Process

Albaugh requests a waiver for this data requirement. Oxyfluorfen TGAI product is not deliberately formulated. See Guideline 830.1620.

Footnote 3

- 830.6317 Storage stability
- 830.6320 Corrosion characteristics

Albaugh is currently conducting combined testing for these guidelines as allowed by OPPTS Product Properties Test Guidelines. Albaugh will submit these studies upon completion of the Storage Stability one year after initiation and requests that a conditional registration be granted prior to submission of the data.

Footnote 4

- 830.7220 Boiling Point/Range

Albaugh requests a waiver for this data requirement. Oxyfluorfen TGAI is a solid.

Footnote 5

- 830.7370 Dissociation Constants in Water

An evaluation of the Oxyfluorfen molecular structure and its neutral pH value indicates that it will not dissociate. An exhaustive public literature search reveals no pKa value is given for Oxyfluorfen. According to The Pesticide Manual, Eleventh Edition, page xix, "where no pKa value is given, it may indicate that no significant dissociation occurs in the environmental range; values of pKa <4 for bases and pKa >8 for acids are not relevant in an environmental context". Accordingly, Albaugh requests a waiver for this data requirement.

Footnote 6

- 830.7550 Partition Coefficient, Shake Flask Method
- 830.7560 Partition Coefficient, Generator Column Method

Albaugh requests a waiver for these data requirements. Albaugh has elected to satisfy this data with the 830.7570 Liquid Chromatography Method.

Footnote 7

- 830.7860 Water Solubility, Generator Column Method

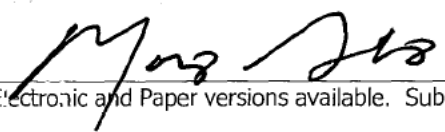
Albaugh requests a waiver for these data requirements. Albaugh has elected to satisfy this data with the 830.7840 Shake Flask Method.

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DATA MATRIX

Date: 8/15/12	EPA Reg. No./File Symbol 42750-135	Page 1 of 6
Applicant's/Registrant's Name & Address: Albaugh Inc. 1525 NE 36 th St. Ankeny, IA 50021	Product: Oxyfluorfen TGAI	
Ingredient: Oxyfluorfen CAS # 42874-03-3		

Guideline Reference	Guideline Study Name	MRID Number	Submitter	Status	Note
				OWN	
				OWN	
				OWN	
					Waiver ²
				OWN	
				OWN	
				OWN	
				OWN	
				OWN	
				OWN	
				OWN	
				OWN	
					Not req'd ¹
					Not req'd ¹
					Not req'd ¹
					In progress ³
Signature 			Name and Title: Morris Gaskins Registrations Manager	Date: 8/15/12	

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DATA MATRIX

Date: 8/15/12		EPA Reg. No./File Symbol 42750-135		Page 2 of 6	
Applicant's/Registrant's Name & Address:		Product:			
Albaugh Inc. 1525 NE 36 th St. Ankeny, IA 50021		Oxyfluorfen TGA1			
Ingredient: Oxyfluorfen CAS # 42874-03-3					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					Not req'd ¹
					In progress ³
					Not req'd ¹
			Albaugh	OWN	
			Albaugh	OWN	
					Not req'd ¹
			Albaugh	OWN	
					Waiver ⁴
			Albaugh	OWN	
					Waiver ⁵
					Waiver ⁶
					Waiver ⁶
			Albaugh	OWN	
Signature			Name and Title: Morris Gaskins Registrations Manager		Date: 8/15/12

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Agency Public Use Copy

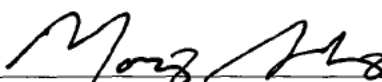
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DATA MATRIX

Date: 8/15/12	EPA Reg. No./File Symbol 42750-135	Page 3 of 6
Applicant's/Registrant's Name & Address: Albaugh Inc. 1525 NE 36 th St. Ankeny, IA 50021	Product: Oxyfluorfen TGAI	

Ingredient: Oxyfluorfen CAS # 42874-03-3

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Albaugh	OWN	
					Waiver ⁷
			Albaugh	OWN	
				PAY	
				PAY	
				PAY	
				PAY	
				PAY	
Signature 			Name and Title: Morris Gaskins Registrations Manager		Date: 8/15/12

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Applicant's/Registrant's Name & Address:		Product:			
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Ingredient: Oxyfluorfen CAS # 42874-03-3					
Guideline Reference Number	Guideline Study Name	MRID	Submitter (EPA Co. No.)	Status	Note
Oxyfluorfen data requirements					
Albaugh will make offers-to-pay to the following companies that appear on the current data submitters list for Oxyfluorfen					
		Ortho/Scotts Company (239)	PAY		
		Dupont (352)	PAY		
		Monsanto (524)	PAY		
		Chemsico (9688)	PAY		
		Agan (11603)	PAY		
		Loveland Products (34704)	PAY		
		Harrell's (52287)	PAY		
		Everris (58185)	PAY		
		OGP (59807)	PAY		
		Dow Agrosiences (62719)	PAY		
		Makhteshim-Agan NA (66222)	PAY		
		Signature		Name and Title: Morris Gaskins Registrations Manager	

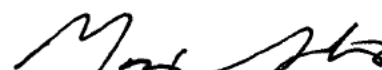
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, DC 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 8/15/12	EPA Reg. No./File Symbol 42750-135	Page 5 of 6
Applicant's/Registrant's Name & Address: Albaugh Inc. 1525 NE 36 th St. Ankeny, IA 50021	Product: Oxyfluorfen TGAI	

Ingredient: Oxyfluorfen CAS # 42874-03-3

Guideline Reference Number	Guideline Study Name	MRID	Submitter (EPA Co. No.)	Status	Note	
			Spray Drift TF (66607)	PAY		
			ORETF (71754)	PAY		
			Ag Reentry TF (71755)	PAY		
			Nations Ag II (72167)	PAY		
			FIFRA ESTF (73989)	PAY		
			REJV (74888)	PAY		
			AG handlers Exposure TF (75234)	PAY		
			Gro-Pro (79676)	PAY		
			Summit Agro NA (82534)	PAY		
			Source Dynamics (82542)	PAY		
			GESTF (84653)	PAY		
			Willowood Oxyfluorfen (87283)	PAY		
			Willowood LLC (87290)	PAY		
			Glorion (87769)	PAY		
			Summit Agro USA (88783)	PAY		
Signature				Name and Title: Morris Gaskins Registrations Manager		Date: 8/15/12

Footnote 1

- 830.6314 Oxidation/Reduction: chemical incompatibility
- 830.6315 Flammability
- 830.6316 Explodability
- 830.6319 Miscibility
- 830.6321 Dielectric Breakdown
- 830.7100 Viscosity

This data is not required for Technical Grade products per Product Properties Test Guidelines OPPTS 830.1000 (e)(2)(xi)(B) Table 2

Footnote 2

- 830.1650 Formulation Process

Albaugh requests a waiver for this data requirement. Oxyfluorfen TGAI product is not deliberately formulated. See Guideline 830.1620.

Footnote 3

- 830.6317 Storage stability
- 830.6320 Corrosion characteristics

Albaugh is currently conducting combined testing for these guidelines as allowed by OPPTS Product Properties Test Guidelines. Albaugh will submit these studies upon completion of the Storage Stability one year after initiation and requests that a conditional registration be granted prior to submission of the data.

Footnote 4

- 830.7220 Boiling Point/Range

Albaugh requests a waiver for this data requirement. Oxyfluorfen TGAI is a solid.

Footnote 5

- 830.7370 Dissociation Constants in Water

An evaluation of the Oxyfluorfen molecular structure and its neutral pH value indicates that it will not dissociate. An exhaustive public literature search reveals no pKa value is given for Oxyfluorfen. According to The Pesticide Manual, Eleventh Edition, page xix, "where no pKa value is given, it may indicate that no significant dissociation occurs in the environmental range; values of pKa <4 for bases and pKa >8 for acids are not relevant in an environmental context". Accordingly, Albaugh requests a waiver for this data requirement.

Footnote 6

- 830.7550 Partition Coefficient, Shake Flask Method
- 830.7560 Partition Coefficient, Generator Column Method

Albaugh requests a waiver for these data requirements. Albaugh has elected to satisfy this data with the 830.7570 Liquid Chromatography Method.

Footnote 7

- 830.7860 Water Solubility, Generator Column Method

Albaugh requests a waiver for these data requirements. Albaugh has elected to satisfy this data with the 830.7840 Shake Flask Method.

Material to be added to an e-Jacket/Jacket

Reg. No. 42750-135

Decision # 449628

Description: newly stamped label

amendment

1. Placement within the e-Jacket/jacket:

☒ Default: (chronological, top = newest)

☐ File Location: (eg. "before page 45 in .pdf")

2. ☐ Send to Data Extraction contractors this material:

☒ Newly stamped accepted label

☐ Notification

☐ New CSF

☐ Other:

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Maggie Rudick

Phone: 703-347-0257

Division: RD

Date: 06/01/11



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Morris Gaskins
Albaugh, Inc.
P.O. Box 2127
Valdosta, GA 31604-2127

JUN 1 2011

Subject: Label Amendments for Container Disposal: Update Container Disposal Instructions Using
Alternate Language from PRN-2007-4
Applications Dated: May 31, 2011

PRODUCT	EPA REG. NO.
Technical Bromoxynil Octanoic Acid	42750-54
Picloram Acid Technical	42750-78
Triclopyr TGAI	42750-123
Imazethapyr TGAI	42750-145
Propazine Technical	42750-149
Dicamba Technical	42750-57
Clopyralid Technical	42750-86
Oxyflourfen TGAI	42750-135
Technical MCPA Acid	42750-213

Dear Mr. Gaskins:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable.

Amended labeling will supersede all previously accepted ones. A stamped copy of labeling is enclosed for your records.

Submit one (1) copy of final printed labeling before you release the products for shipment. If you have any questions regarding this letter, please contact Maggie Rudick at (703) 347-0257 or rudick.maggie@epa.gov.

Sincerely,

Kable Bo Davis
Product Manager 25
Herbicide Branch
Registration Division (7505P)

OXYFLUORFEN TGAI

For Manufacturing Use Only

ACTIVE INGREDIENT:

Oxyfluorfen: 2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl) benzene 97.0%

INERT INGREDIENTS: 3.0%

TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Evacuation of the stomach might be advisable.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may contact 1-800-424-9300 day or night, for emergency medical or transport information.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

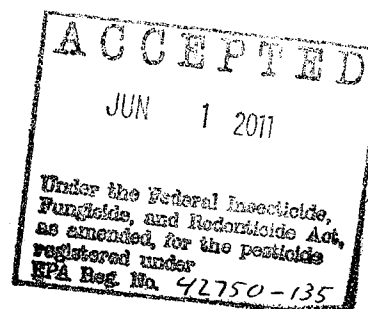
CAUTION. Harmful if Swallowed. Causes Moderate Eye Irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

EPA Reg. No. 42750-135

EPA Est. No. xxxxxx-xxx-xxx

NET CONTENTS: ____ Kg.

Manufactured For:
ALBAUGH, INC.
ANKENY, IA 50021



ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, ocean or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE: Keep away from fire and sparks. Store in a cool, dry and well-ventilated area.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Non-refillable container. DO NOT reuse or refill this container.

Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. If not emptied in this manner, the liner may be considered an acute hazardous waste and disposed in accordance with local, state and federal regulations.

When completely empty, offer for recycling, if available, or dispose of liner in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. If drum or other outer container is contaminated and cannot be reused, dispose of in the manner required for its liner.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into a herbicide for the following use(s):

Artichokes (globe), broccoli, cabbage, cauliflower. Cacao, citrus (non-bearing), coffee, conifers (seedbeds, transplants, container stock) and selected deciduous trees, corn, cotton, cottonwood, eucalyptus, fallow bed (cotton/soybeans), fallow land, garbanzo beans, garlic, guava (Hawaii only), horseradish, jojoba, mint, onions, onions grown for seed, papayas (Hawaii only), soybeans, taro, and tree fruit, nuts, and vines (which includes almond, apple, avocado, beechnut, brazil nut, butternut, cashew, chestnut, chinquapin, crabapple, date, feijoa, fig, filbert, grapes, hickory nut, kiwi, loquat, macadamia nut, mayhaw, nectarines, olives, peach, pear, pecan, persimmon, pistachio, plum, pomegranates, prune, quince, walnut).

This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).

It is the responsibility of the formulator to supply data to EPA to support all claims listed on the formulator's label covering all directions for use. Formulators should consult Albaugh for formulation information.

NOTE: OXYFLUORFEN TGA should be melted by holding at 110° C for 48 hours. DO NOT HEAT

ABOVE 200° C (PRODUCT DECOMPOSES)

WARRANTY LIMITATIONS AND DISCLAIMER

ALBAUGH warrants that at the time of delivery, the product will conform to its chemical description on the label, that it will pass without objection in the trade under the contract description, that seller will convey good title thereto, and that such product will be delivered free from any lawful security interest, lien or encumbrance.

ALBAUGH EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND, EXCEPT AS SET FORTH IN THE ABOVE PARAGRAPH, ANY OTHER EXPRESS OR IMPLIED WARRANTIES. Buyer acknowledges the use of its own independent skill and expertise in the selection and use of the product and does not rely on any oral or written statements or representations.



RE: Technical labels
Morris Gaskins to: Maggie Rudick

05/31/2011 04:42 PM

Maggie,

Clean versions attached. If anything needs changing on any of them let me know.

Thanks for your help on this.

Also, I've not forgotten about the emailed comments on our Glyphosate 41% label Container Disposal you sent back last week. I will probably run a revised version incorporating the suggested changes back by you before submitting.

Regards,

Morris

-----Original Message-----

From: Rudick.Maggie@epamail.epa.gov [mailto:Rudick.Maggie@epamail.epa.gov]
Sent: Tuesday, May 31, 2011 3:40 PM
To: Morris Gaskins
Subject: Technical labels

Hi Morris-

I was just reviewing your label amendments for the following products and everything looks fine, we just need clean labels to stamp for our filing.

Thank you and have a nice afternoon!

PRODUCT	EPA REG. NO.
Technical Bromoxynil Octanoic Acid	42750-54
Dicamba Technical	42750-57
Picloram Acid Technical	42750-78
Clopyralid Technical	42750-86
Triclopyr TGAI	42750-123
Oxyflourfen TGAI	42750-135
Imazethapyr TGAI	42750-145
Propazine Technical	42750-149
Technical MCPA Acid	42750-213

Re: Albaugh 2007-4 Labeling 

Nancy Fitz to: Maggie Rudick, Jeanne Kasai

05/31/2011 09:40 AM

History: This message has been replied to.

Hi Maggie,

Jeanne and I reviewed these and have the following comments and suggestions for these labels.

Page 2 - Bromoxynil (42750-54)

- This has the three "container type" statements for nonrefillable containers.
- Based on the assumption that this is not a dilutable pesticide (most technical products are not), the regulations do not require a residue removal statement. They can include one, like they did, and it's good that they used a statement from the regs "Triple rinse (or equivalent) promptly after emptying." Again, it is optional for them to include it, but it does seem like a good idea based on the statement "If not triple rinsed, these containers are acute hazardous wastes..." If they do include these instructions to triple rinse the container, it would be good to also include instructions for what to do with the rinsate. The rinsate management instructions from our standard triple rinse instructions are "Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal." but those don't really work in this situation. Maybe something like "Use rinsate in the pesticide formulation or dispose of in accordance with local, state and federal regulations." or Albaugh can suggest an alternative.
- We recommend that you look through the full label to confirm that this is not dilutable. The definition in §156.3 is: "Dilutable means that the pesticide product's labeling allows or requires the pesticide product to be mixed with a liquid diluent prior to application or use."
- Bottom line: Confirm that the product is not dilutable and add instructions for what to do with the rinsate.

Page 3 - Propazine (42750-149)

- This has the three "container type" statements for nonrefillable containers.
- Based on the assumption that this is not a dilutable pesticide (most technical products are not), the regulations do not require a residue removal statement. The statement that they included is adapted from the instructions for fiber drums with liners in Chapter 13 of the Label Review Manual and makes sense.
- We recommend that you look at the full label to confirm that this is not dilutable. The definition in §156.3 is: "Dilutable means that the pesticide product's labeling allows or requires the pesticide product to be mixed with a liquid diluent prior to application or use."
- The last sentence in the first full paragraph seems to be missing "must be" in "...the liner may be considered an acute hazardous waste and MUST BE disposed in accordance..."
- Bottom line: Okay as is, after confirming it is not dilutable but recommend the editorial change in the previous bullet.

Let us know if you have any questions about these suggestions.

Nancy Fitz
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 305-7385 (phone)
(703) 308-2962 (fax)
fitz.nancy@epa.gov (e-mail)
Pesticide container & containment web site: <http://www.epa.gov/pesticides/regulating/containers.htm>

Maggie Rudick

Hi Nancy- Thank you so much for your help with...

05/26/2011 02:35:53 PM

From: Maggie Rudick/DC/USEPA/US
To: Nancy Fitz/DC/USEPA/US@EPA

Date: 05/26/2011 02:35 PM
Subject: Albaugh 2007-4 Labeling

Hi Nancy-

Thank you so much for your help with these storage and disposal statements! I don't know why I'm having so many issues with them lately.

I attached 3 papers below- the

1st- cover letter explaining why they cannot follow the language in 2007-4

2nd- 2nd page of Bromoxynil label (Reg No 42750-54)

3rd- 2nd page of Propazine label (Reg No 42750-149) - the language is exactly the same with 8 other technical product submissions which came in at the same time.

If you want to see the full labels, just let me know, wasn't sure what was easiest for you.

Thank you!

Maggie L. Rudick
Environmental Protection Specialist
Herbicide Branch; Registration Division
Environmental Protection Agency
(703) 347-0257
Rudick.Maggie@epa.gov

----- Forwarded by Maggie Rudick/DC/USEPA/US on 05/26/2011 02:31 PM -----

From: cts/cts/QP/USEPA/US@EPA
To: Maggie Rudick/DC/USEPA/US@EPA
Date: 05/26/2011 02:28 PM
Subject:



[Untitled].pdf

CORPORATE OFFICE
1525 NE 36th Street
Ankeny, IA 50021
515.964.9444 (Phone)
800.247.8013 (Toll Free)
515.964.7813 (FAX)

ALBAUGH, INC.

GEORGIA OFFICE
P.O. Box 2127
Valdosta, GA 31604-2127
229.244.3288 (Phone)
229.244.5841 (FAX)

Fed-X

May 23, 2011

Document Processing Desk (AMEND)
Mr. Bo Davis (PM 25)
Registration Division
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard (South Bldg)
2777 South Crystal Dr.
Arlington, VA 22202

RE: Label amendments for Container Disposal

Dear Mr. Davis,

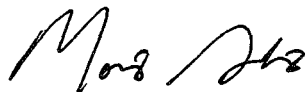
The enclosed submissions for the listed registrations are label amendments to revise the Container Disposal text in response to the Agency's rejection letter to previously submitted notifications under PR Notice 2007-4. These registrations are technical products that do not lend themselves to the PR Notice template. Accordingly, we reviewed the Agency's Label Review Manual in addition to the PR Notice for guidance on appropriate language.

These products are not dilutable with water and except for the Bromoxynil Technical, are packaged in large bulk tote bags with plastic liners. Only the liners are left with any residue after emptying and are disposed of according to appropriate regulations for the particular chemical. The Bromoxynil Technical is received in open mouth unlined metal drums which are also disposed of appropriately after emptying.

PRODUCT	EPA REG. NO.
Technical Bromoxynil Octanoic Acid	42750-54
Dicamba Technical	42750-57
Picloram Acid Technical	42750-78
Clpyralid Technical	42750-86
Triclopyr TGAi	42750-123
Oxyfluorfen TGAi	42750-135
Imazethapyr TGAi	42750-145
Propazine Technical	42750-149
Technical MCPA Acid	42750-213

Please call if you have any questions.

Regards,



Morris Gaskins
Registrations Manager
Albaugh, Inc.

Agri Star™
By Albaugh, Inc.

PREMIER SUPPLIER OF OFF-PATENT CROP PROTECTION PRODUCTS
www.albaughinc.com



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 42750-135	2. EPA Product Manager Mr. Bo Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Oxyfluorfen TGA1	PM# 25	
5. Name and Address of Applicant (Include ZIP Code) Albaugh Inc. P.O. Box 2127 Valdosta, GA 31604 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated <u>4/26/11</u>	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Label amendment for Container Disposal that deviates from PR Notice 2007-4.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 200 kg		5. Location of Label Directions <input checked="" type="checkbox"/> On label attached to container	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Morris Gaskins		Title Registrations Manager		Telephone No. (Include Area Code) 229-214-3288	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment, or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Registrations Manager			
4. Typed Name Morris Gaskins		5. Date May 23, 2011			

Material to be added to an e-Jacket/Jacket

Reg. No. 42750-135

Decision # 448178

Description:

Unacceptable Notification

1. Placement within the e-Jacket/jacket:

☒ Default: (chronological, top = newest)

☐ File Location: (eg. "before page 45 in .pdf")

2. ☐ Send to Data Extraction contractors this material:

☐ Newly stamped accepted label

☐ Notification

☐ New CSF

☒ Other: _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Maggie Rudick

Division: RD

Phone: 307-347-0257

Date: 04/26/11



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. Morris Gaskins
Albaugh, Inc.
P.O. Box 2157
Valdosta, GA 31604-2127

APR 26 2011

Subject: NOTIFICATION CHANGES (EPA REG. NO. 42750-54, 42750-57, 42750-78, 42750-86, 42750-123, 42750-135, 42750-145, 42750-149, 42750-200, and 42750-213)

Dear Mr. Morris:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 dated April 12, 2011 for the following products:

Technical Bromoxynil Octanoic Acid
Dicamba Technical
Picloram Acid Technical
Clopyralid Technical
Triclopyr TGA1

Oxyflourfen TGA1
Imazethapyr TGA1
Propazine Technical
Triclopyr 44% TEA MUP
Technical MCPA Acid

The Registration Division (RD) has conducted a review of this request for its applicability under PRN 2007-4 and finds that the action(s) requested does not clearly fall within the scope of PRN 2007-4 and will require additional administrative review of the related files. A summary of our findings include:

- 1. Language needs to comply with 'Table 3. Recommended Container Handling Statements for Pesticide Products that are Acute Hazardous Waste When Discarded: For non-refillable bags of granular or dry formulation' of the Label Review Manual. (Page 179)**

Please be advised that PRNs are provided as guidance; they are not considered regulation by the Agency. Therefore, the RD reserves the right to make the above determination and concludes that this action must be submitted by you as an amendment. No further processing of this action will occur until a resubmission is made. The RD has determined that this action is denied and our records have been updated accordingly.

If you have any questions regarding this letter, contact Maggie Rudick at (703) 347-0257 or rudick.maggie@epa.gov.

Sincerely,

Kable Bo Davis, Product Manager 25
Herbicide Branch
Registration Division (7505P)

CORPORATE OFFICE
1525 NE 36th Street
Ankeny, IA 50021
515.964.9444 (Phone)
800.247.8013 (Toll Free)
515.964.7813 (FAX)

ALBAUGH, INC.

GEORGIA OFFICE
P.O. Box 2127
Valdosta, GA 31604-2127
229.244.3288 (Phone)
229.244.5841 (FAX)

Fed-X

April 12, 2011

Document Processing Desk (NOTIFY)
Ms. Kay Montague (PM 23)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

RE: PR Notice 2007-4

Dear Ms. Montague,

The enclosed submission for the below referenced registration is a label notification in response to the Agency's PR Notice 2007-4 for Container Disposal revision.

PRODUCT	EPA REG. NO.
Oxyfluorfen TGAI	42750-135 ✓
Technical Ester of MCPA	42750-214
Dicamba Technical	42750-57
Clpyralid Technical	42750-86
Technical MCPA Acid	42750-213

Three copies of the draft label with changes noted with strikeout/bold text are enclosed. The PRN certification statement is listed on the 8570-1 forms.

Please call if you have any questions.

Regards,



Morris Gaskins
Registrations Manager
Albaugh, Inc.

Agri Star™
By Albaugh, Inc.

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www.albaughinc.com



United States
Environmental Protection Agency
Washington, DC 20460

☐
☐
☒

Registration
Amendment
Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 42750-135	2. EPA Product Manager K. Montague	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Oxyfluorfen TGA1	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) Albaugh Inc. P.O. Box 2127 Valdosta, GA 31604-2127 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Label notification to revise Container Disposal instructions under PR Notice 2007-4 as amended April, 2008. (~~Replaces original notification of 9/24/00~~) This notification is consistent with the provisions of PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under section 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
					4
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 200 Kg 2.5 gal, 30 gal, bulk		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Morris Gaskins	Title Registrations Manager	Telephone No. (Include Area Code) 229-244-3288
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Registrations Manager	
4. Typed Name Morris Gaskins	5. Date 4/12/11	

